

were used. Participants were surveyed about: a) effectiveness of individual courses and instructors; b) convenience of courses being offered at the Annual Meeting; c) pros and cons of the courses; and d) the numbers and hours taken by participants in different sub-populations. A break-even analysis was done to determine the number of participants who need to attend a course before ISPOR can recover its fixed costs. **RESULTS:** Three hundred one people (12% non-members, 11% non-USA based) took 538 courses at the Annual Meeting, and the response rate to the survey was 58%. New courses and suggestions were offered for improving the quality. A break-even analysis determined that 17 people were needed for new courses. The average number and duration of courses was 1.79 and 8.7 hours respectively. There was no difference in results between members and non-members, or between USA and non-USA participants, but hours differed significantly based on participant setting. The courses were considered useful by 95% and recommended by 91% of respondents. **CONCLUSIONS:** Strong interest in adding new courses and increasing the complexity of existing courses shows that opportunities exist for expansion by adding courses and increasing the number of 8 hour courses. Specific marketing plans should be developed to increase the average number of courses/hours taken by attendees. Live courses should continue to be offered in conjunction with the Annual Meeting to promote ISPOR membership and attendance at the Annual Meeting. Existing course instructors should continue to add more cases, workshop sessions, and involve the participants in active learning.

METHODOLOGICAL ISSUES—Quality of Life Studies

PMD37

RECOMMENDATIONS TO THE EUROPEAN REGULATORS FOR THE CROSS-CULTURAL ADAPTATION OF PRO MEASURES

Conway K, Mear I, Acquadro C

Mapi Research Institute, Lyon, France

Introduction With the growing use of Patient-Reported Outcomes (PROs) questionnaires for the evaluation of medicines in Europe, the need for international measures has increased. In response to European regulators' concerns about the methodology used to achieve cultural adaptation of PRO measures, the ERIQA Group and Mapi Research Institute have investigated current guidelines. **OBJECTIVES:** To identify and review the methods used for cultural adaptation of PRO measures, to propose recommendations of best practice to European regulators. **METHODS:** Relevant papers were identified from Medline, Embase, and Mapi Research Institute's database. The databases were explored with "quality of life", "questionnaires", "health status indicators" matched with "translating", "cross-cultural comparison", "translations issues" and "cross-cultural research". Papers pub-

lished between January 1966 and April 2001 were considered. 415 abstracts were reviewed. Papers were included if they proposed guidelines or recommendations and/or they reviewed and criticised methods. **RESULTS:** Thirty-two papers met the inclusion criteria. We identified 14 sets of guidelines. The review highlighted a lack of consensus regarding the terminology to qualify the process of adapting a PRO measure from a source to a target language, and the scope covered by this terminology. Common points included multiple forward translations, reconciliation sessions, some form of back-translations and psychometric validation. Differences were seen in the importance given to back-translation, focus groups, cognitive debriefing, and recruitment criteria for translators. With only two articles comparing methodologies, the review could not determine the best method to apply among the 14 identified. **CONCLUSION:** This review demonstrates disparity in definitions and methods. There is no evidence proving that one method leads to better results than another. We propose providing regulators with an overview of what most investigators recommend as minimum requirements. This proposal will be presented in the form of a checklist including a maximum of 12 steps from concept definition to psychometric evaluation, depending on the target culture and/or language and type of PRO.

PMD38

WORST AND BEST EYE VISUAL ACUITY CONSEQUENCES ON VISION-RELATED QUALITY OF LIFE IN PATIENTS SUFFERING FROM AGE RELATED MACULAR DEGENERATION

Nordmann J¹, Berdeaux G²

¹Quinze-Vingts Centre Hospitalier National d'Ophtalmologie, Paris, France; ²Alcon, Rueil-Malmaison, France

OBJECTIVE: To evaluate the vision-related quality of life (QoL) consequences of the best and the worst eye, respectively, in patients suffering from age related macular degeneration (AMD). **METHODS:** One hundred fourteen patients with a diagnosis of exudative AMD and a primary or recurrent subfoveal neovascular membrane (<5400 µm in its greater dimension; >50% choroidal neovascularization representing >1 mm²) were included. ETDRS visual acuity (VA in LogMAR) was measured in both eyes separately. Vision-related QoL was assessed using the NEI-VFQ-39 (13 scores from 0 to 100). An analysis of variance was performed on the QoL scores, including best eye (VA > 0.3), worst eye (VA > 1), and their interaction. **RESULTS:** Best eye VA was 0.34 on average and 43.0% had a VA > 0.3. Worst eye VA was 0.85 on average and 32.5% had a VA > 1. VA was not linked to general health and ocular pain scores. General vision, near activities, distance vision, driving, mental health, role difficulties, dependency, peripheral vision and the global scores were affected both by best eye VA

(−10.2 to −47.4) and by worst eye VA (−6.9 to −20.0). An interaction was found on social functioning score: QoL loss was most important when worst eye VA was higher than 1 (−1.1 versus −18.5). Worst eye contributed from 19.9% to 47.4% of the total QoL loss. **CONCLUSION:** Worst and best eye VA contributed independently to vision-related QoL. Under isotropic hypothesis, preserving VA on the worst eye should contribute to maintain vision-related QoL on the long term.

PMD39

DESCRIPTION OF THE PRINCIPLES OF GOOD PRACTICE FOR TRANSLATION AND CULTURAL ADAPTATION OF PRO MEASURES: ISPOR QOLSIG GROUP

Wild DJ¹, Ford S², Martin M³, Eremenco S⁴, Verjee-lorenz A¹

¹Oxford Outcomes Ltd, Cassington, Oxford, United Kingdom;

²Pfizer Global Pharmaceuticals, Kalamazoo, MI, USA; ³Health Research Associates, Inc (HRA), Seattle, WA, USA; ⁴Evanston Northwestern Health care, Evanston, IL, USA

OBJECTIVES: A series of quality of life special interest groups were set up by ISPOR in 1999. The translation and cultural adaptation group has met six times and has been working towards a set of Principles of Good Practice. **METHODS:** The translation and cultural adaptation process was divided into requisite components: forward translation and reconciliation, back translation, harmonisation, and cognitive debriefing and each component was given to a member of the working group. The working group took a consensus of the guidelines and using their knowledge and experience to summarise and suggest the criteria for achieving success. The draft document was then reviewed by all of the members of the QoL special interest groups at ISPOR. **RESULTS:** Eleven sets of guidelines were identified and critiqued. The document produced by the group is tabular in format and includes four columns: name of step, key components, rationale, and risks of failing to complete the step. **CONCLUSION:** The document is now being submitted for publication. Further work will continue in order to expand the document to include discussion of a wide range of PRO's and cultural adaptation of translations where an existing version exists but which has been developed for use in another culture.

PMD40

UTILISATION OF THE FOCUS GROUP TECHNIQUE IN THE DEVELOPMENT OF QUALITY OF LIFE QUESTIONNAIRES

Barea N¹, Garcia S¹, Perulero N¹, Sarmiento M¹, Badia X²

¹HOTrials (Health Outcomes Research Europe Group), Barcelona, Spain; ²Health Outcomes Research Europe Group, Barcelona, Spain

The Focus Group(FG)technique is a discussion forum that allows the access to valuable information generated

by a group of people under controlled conditions. This is especially useful to explore complex health and psychology-related topics. Moreover, it has the advantage of being fastest and less expensive than individual interviews and qualitative research techniques. It has also the advantage of incorporating the patients' perspective into the problem analysis and facilitating the interaction to obtain information that would be otherwise inaccessible. In addition, patient's intervention helps to explore new dimensions of the problem as well as to generate creative ideas giving room for spontaneity and flexibility. Nevertheless, and despite of these theoretical advantages the incorporation of the FG technique into the development of QoL questionnaires is apparently somewhat low. **OBJECTIVES:** To investigate the level of utilisation of the FG technique in the development of health related QoL questionnaires. **METHODS:** A systematic search of the Medline database from 1993–2003 has been performed. The descriptors used were "quality of life", "questionnaire" and "focus group". **RESULTS:** Our search indicated that from 67 studies that met our search criteria only 16 used the qualitative technical of FG in the phase of the development of QoL questionnaires. It is important to point out that 10 out of these 16 publications, in which the FG technique was used, were published during the last 3 years, showing a positive trend. **CONCLUSIONS:** Although in the last years there has been a slight increase in the use of FG technique, we consider that it would be necessary to emphasize the importance of this qualitative technique into the development of the QOL questionnaires. This would enhance the active role of patients, taking into account both, incorporation of the patient's perspective into the analysed problem and identification of other aspects more difficult to approach by the clinician.

PMD41

THE NATURE OF THE QUALITY-ADJUSTED LIFE YEAR (QALY) CALCULATION

Prieto L¹, Sacristan JA²

¹Eli Lilly & Co, Alcobendas, Madrid, Spain; ²Eli Lilly & Co., Spain, Alcobendas, Madrid, Spain

OBJECTIVES: The quality-adjusted life-year (QALY) is a measure of the value of health outcomes. Since health is a function of length of life and quality of life (QoL), the QALY was developed as an attempt to combine the value of these attributes into a single index number. Nevertheless, QALYs have been criticised on technical and ethical grounds. A salient problem relies on the numerical nature of its constituent parts. The appropriateness of the QALY arithmetical operation is compromised by the essence of the utility scale: while life-years are expressed in a ratio scale with a true zero, the utility is an interval scale where 0 is an arbitrary value for death. In order to be able to obtain coherent results, both scales would have to be expressed in the same units of measurement. The differ-